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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,819	11/06/2000	Akira Aomatsu	5774-01-MJA	5038

7590

11/01/2002

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EXAMINER

JARVIS, WILLIAM R A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 11/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,819

Applicant(s)

AOMATSU, AKIRA

Examiner

William R. Jarvis

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 20, and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. In view of applicant's amendment and remarks filed 12 August 2002, the rejection under 35 U.S.C. 112, 2nd paragraph is withdrawn.

Claims 1-17, 20, and 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's submitted references U.S. Patents 5,025,035 (Wallace) or 5,084,479 (Woodruff), European Patent 458,751, or the patent abstract of Japanese Patent 63253022. Wallace and Woodruff disclose pharmaceutical compositions of gabapentin and other 4-amino-3-substituted-butanoic acid derivatives with applicant's preferred humectants propylene glycol, glycerin, and sorbitol; see col. 2, lines 13-57 of Wallace and col. 3, line 35 to col. 4, line 12 of Woodruff in particular. European Patent 458,751 disclose compositions of gabapentin and related compounds with excipients including sorbitol, monoglycerides, diglycerides, and triglycerides; see page 4, line 55 to page 5, line 51. The Japanese patent abstract discloses compositions of applicant's preferred compound baclofen with propylene glycol as an excipient. Some claims differ in that they require humectants such as ethylene and butylene glycol which are not taught by the prior art. However, since these are conventional humectants in the pharmaceutical arts, it would have been obvious to one skilled in the art to employ them in the claimed compositions. The claimed amounts are obvious since it is within the skill of the pharmaceutical artisan to determine the amount of drug that provides the therapeutic effect most effective for treating the patient's condition while minimizing adverse side effects.

Applicant's remarks filed 12 August 2002 regarding the obviousness rejection have been carefully considered, but are not persuasive. The remarks regarding the European Patent are not persuasive since the reference specifically discloses the combination of gabapentin with glycerol monostearate (an aliphatic acid ester of glycerol of present claims 2, 6, and 13) in tables II and IV on pages 8 and 9. Although Wallace and Woodruff do not disclose specific examples of the claimed compounds with one of the claimed humectants, the two references clearly suggest that applicant's preferred humectants propylene glycol, glycerin, and sorbitol are suitable pharmaceutical carriers for the compounds as discussed *supra*. The Japanese patent abstract clearly discloses the combination of applicant's preferred compound baclofen with the preferred humectant propylene glycol. Although none of the prior art references specifically suggest the

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stabilizing effect or avoidance of degradation by using a humectant, the references clearly teach that many of the claimed humectants are appropriate carriers for the claimed compounds. It is not necessary that the prior art teach the intended purpose of the humectant (i.e. to manufacture small, stabilized compositions containing high concentrations of active ingredients) to make the claims obvious. Accordingly, the claims remain rejected by the prior art of record.

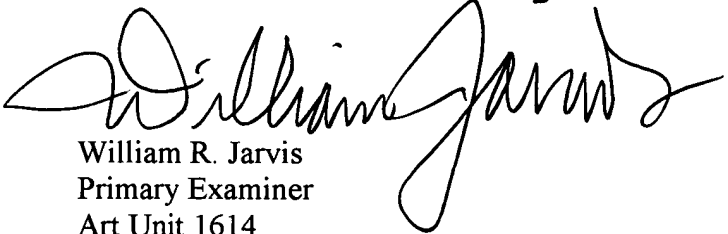
3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William R. Jarvis whose telephone number is 703-308-4613. The examiner can normally be reached on Monday, Tuesday, Thursday & Friday 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne C. Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


William R. Jarvis
Primary Examiner
Art Unit 1614

wrj
October 30, 2002